UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/579,982	05/26/2000	James L. Winkler	03848-00005	1925

7590 10/22/2003

John P Iwanicki
BANNER & WITCOFF
28 State Street
28th Floor
Boston, MA 02109

EXAMINER	
LUDLOW, JAN M	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 10/22/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/579,982	WINKLER ET AL.	
	Examiner	Art Unit	
	Jan M. Ludlow	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *48-151* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *22 May 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 48-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanz in view of Meltzer.

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Sanz fails to teach a positioning device or a polymer solution.

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in order to dispense small volumes precisely into container arrays as taught by Meltzer. With respect to a source of polymer, it would have been obvious to provide a solution of DNA, RNA or proteins in order to provide a biological sample as taught by Sanz. With respect to the number of areas in the array, it would have been obvious to provide as many supports, such as microtiter trays, as required.

5. Claims 48-81, 83-91, 93-111, 113-139, 141-143, 145-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hayes in view of Prats.

Hayes teaches an ink jet printer for printing reagents. Droplets of 100 picoliters to 1 microliter are produced. Multiple dispensers 400 and movement between the print head(s) and substrate are used.

Hayes fails to teach positioning of the print head.

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the monomers in the invention of Pirrung using an inkjet print with plural heads and relative motion means in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being

suitably an inkjet printer as taught by Southern and Hayes. With respect to claims limited to pipettes, it would have been obvious to use a micropipette in place of a print jet in order to deliver similar volumes as taught by Sanz. It would have been obvious to provide the dispenser spaced form the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats. With respect to a source of polymer, it would have been obvious to provide a solution of DNA, RNA or proteins in order to provide biological reagents for testing as was known in the art. With respect to the number of areas in the array, it would have been obvious to provide a large plurality of spots for production of large batches of test devices.

6. Claims 48-81, 83-91, 93-111, 113-139, 141-143, 145-151 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung (WO/90/15070) in view of Southern (WO 89/10977) and Hayes and Prats.

Pirrung et al teach a method for forming arrays of biological polymers by coating a substrate with a protected linker, using a mask to deprotect in desired areas, adding an optionally protected monomer, reacting with the linker and repeating the steps to form an array (See, e.g., p. 4-7; pages 14-16, page 18 and page 28).

Pirrung fails to teach depositing by a dispenser as claimed.

Southern teaches a method similar to that of Pirrung. An ink jet printer may be used to deposit monomers (p. 11).

Hayes teaches an ink jet printer for printing reagents. Droplets of 100 picoliters to 1 microliter are produced. Multiple dispensers 400 and movement between the print head(s) and substrate are used.

Hayes fails to teach positioning of the print head.

Prats teaches precise positioning of a print head in X, Y and Z directions to enhance printing (col. 1, lines 38-55) using an optical positioning system.

It would have been obvious to provide the monomers in the invention of Pirrung using an inkjet print with plural heads and relative motion means in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being suitably an inkjet printer as taught by Southern and Hayes. With respect to claims limited to pipettes, it would have been obvious to use a micropipette in place of a print jet in order to deliver similar volumes as taught by Sanz. It would have been obvious to provide the dispenser spaced form the surface in order to permit drop formation and to provide means to move the dispenser relative to the substrate in order to provide art recognized equivalent to moving the substrate relative to the dispenser as taught by Prats.

7. Claims 82, 92, 112, 140, 144 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pirrung in view of Sanz and Meltzer.

8. Pirrung fails to teach a pipet or pluraility of pipets.

Sanz teaches a micropipet for dispensing 1 nl of biological fluids (col. 1, lines 5-12).

Meltzer teaches a positioning device for pipets for pipetting small volumes. The pipets are precisely located in the X-Y-Z dimensions (col. 1, lines 50-60) by a computer using optical, magnetic or other position detectors (col. 8, lines 1-10).

9. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the pipet of Sanz with the positioning device of Meltzer in the method of Pirrung in order to provide the monomers by known means as taught by Pirrung on page 4, the known means being dispenser(s) of small volumes precisely into arrays as taught by Sanz and Meltzer.

Applicant's arguments filed July 31, 2003 have been fully considered but they are not persuasive.

Applicant argues that it would not have been obvious to automate the manual pipet of Sanz, but the pipet of Sanz is shown as mountable for use (Figures 14, 15), and Meltzer teaches moving such mounted pipets for filling container arrays. Note that the instant claims do not preclude containers as substrate for the array. Applicant argues that the complex method of use teaches away form automation, but the mechanical devices of Sanz are structurally capable of being driven by well-known mechanical expedients, such as stepper motors, etc. Applicant makes arguments concerning the dispenser of Meltzer, but Meltzer has been relied upon for teaching the conventionality of positioning a dispenser, not the features of the dispenser itself. Meltzer teaches an array of dispensers or pipets. Biological polymers would have been obvious to pipet for their known use in biochemical analysis. With respect to the material of the support and

size of the localized areas, the support and its properties as they relate to droplet spreading are not seen to limit the dispensing apparatus.

Applicant argues that Hayes does not teach polymeric reagents, but Hayes teaches toward blood typing and allergen reagents (col. 18, lines 26-31), which would teach or suggest antibodies and/or DNA. Applicant argues that filter paper test strips are not arrays, but points to no teaching in the specification or claims that the arrays cannot be on filter paper, or how the use of filter paper as a substrate limits the dispensing apparatus it self. Applicants comment with respect to Prats are not understood in that applicant acknowledges that Prats teaches adjusting the print head in the X, Y and Z directions (p. 10, paragraph 3). Note further that the instant claims do not require X, Y, Z positioning, but merely positioning per se, and it would have been obvious to provide an ink jet printer with positioning relative to the printing substrate as was known in the art so as to print elements as distinct elements, rather than all superimposed at a single spot.

Applicant argues that Southern provides a mere invitation to experiment, but in that Hayes teaches ink jet printing of "a high density matrix with a variety of reagents as isolated matrix elements" (col. 14, lines 7-10), there is a reasonable expectation of success given the state of the prior art.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Jan M. Ludlow
Primary Examiner
Art Unit 1743

jml
October 20, 2003